

**CLAIMS**

- 1) Powders for inhalation of insulin obtained by spray drying a clear solution of insulin at pH under the isoelectric point of insulin where the 90% of microparticles showing particle size lower than 9  $\mu\text{m}$  as volume diameter.
- 5 2) Powders for inhalation of insulin obtained as Claim 1 having packing characteristics measured as tapped density lower than 0.2  $\text{g/cm}^3$ .
- 3) Powders for inhalation of insulin obtained by spray drying a clear solution of insulin at pH under the insulin isoelectric point having microparticles showing particle shape defined corrugated or raisin like.
- 10 4) Powders for inhalation of insulin obtained by spray drying a clear solution of insulin at pH under the insulin isoelectric point having respirable fraction measured as fraction lower than 5  $\mu\text{m}$  as aerodynamic diameter was more than 80%
- 5) Microparticles according to claim 1 where a clear solution of insulin and excipients having a pH under the isoelectric point of insulin is spray dried.
- 15 6) Microparticles according to claim 1 where the insulin solutions from which they are obtained have a pH preferably lower than 5.4.
- 7) Microparticles according to claim 1 where the preferred excipients are saccharides, polysaccharides, aminoacids, phospholipids and polyalcohol the more preferred of them is mannitol.
- 20 8) Microparticles according to claim 1 where the acid used for dissolution of insulin is a mineral acid such as 0.01 N hydrochloric acid.
- 9) Microparticles obtained by spray drying a clear acidic solution of a therapeutic drug where the volatile organic acids used for dissolution of the said drug are partially evaporated during spray drying leaving particles that dissolved in distilled water give rise to a solution having pH higher than the original value.
- 25 10) Microparticles according to claim 1 where the acid used for dissolution of insulin is a volatile organic acid.
- 11) Microparticles according to claim 1 where the acids are used for dissolution of insulin is a volatile organic acid as diluted acetic acid.
- 30 12) Microparticles according to claim 1 consisting essentially of insulin and the salts formed from the acids used for the insulin dissolution.

- 13) Microparticles according to any claim from 1 wherein the microparticles contain less of 10 % salt by weight of total solids.
- 14) Microparticles according to claim 1 where the insulin is amorphous.
- 15) Microparticles according to previous claims having a particle size in the  
5 respiratory range allowing therapeutic application through administration to the lung.
- 16) A process according to claim 1 wherein the solution to be spray dried contains from 5 up to 100 mg per ml of insulin.